

Division of

Extramural Activities

1986 Annual Report

October 1, 1985-
September 30, 1986

U.S. DEPARTMENT
OF HEALTH
AND HUMAN SERVICES

National
Institutes of
Health

National
Cancer
Institute

Bethesda,
Maryland 20892

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NATIONAL CANCER INSTITUTE
DIVISION OF EXTRAMURAL ACTIVITIES
ANNUAL REPORT

October 1, 1985 - September 30, 1986

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OFFICE OF THE DIRECTOR

The Division of Extramural Activities (DEA) is that component of the National Cancer Institute (NCI) which administers and directs the Institute's grant and contract review and processing activities; provides initial technical and scientific merit review of grants and contracts for the Institute; represents the Institute on overall NIH extramural and collaborative program policy committees, coordinates such policy within NCI, and develops and recommends NCI policies and procedures as related to the review of grants and contracts; coordinates the Institute's review of research grant and training programs with the National Cancer Advisory Board (NCAB); coordinates the implementation of committee management policies within the Institute and provides the Institute's staff support for the National Cancer Advisory Board (NCAB); coordinates program planning and evaluation in the extramural area; provides scientific reports and analyses to the Institute's grant and contract programs; and coordinates and administers the extramurally supported segment of this Institute's participation in minority research and training efforts.

The Division currently consists of the Office of the Director, four branches, and the Comprehensive Minority Biomedical Program (CMBP). A current organizational chart is shown in Figure 1.

Director. In addition to having primary responsibility for the day-to-day planning, direction, implementation, and evaluation of the activities of the Division, the Director has been involved in four important major interfaces with: (1) the NIH extramural community representing NCI through membership in the Extramural Program Management Committee (EPMC), (2) the NCI Program staff, through regular meetings with the divisional chiefs of program directors (CPDs), (3) the National Cancer Advisory Board, as executive secretary--the Board has responsibility for the second phase of the grant dual review process and in this role advises the Director, NCI, on policy matters regarding cancer research and training programs and planning and operation of the National Cancer Program, and (4) the cancer research community which NCI supports through its extramural programs and whose members serve in an advisory capacity on Institute peer review committees and scientific boards.

Deputy Director. The Deputy Director shares responsibility with the Director for the day-to-day scientific and administrative management of the Division and is directly responsible for the continuous review and evaluation of the Division's peer review operations as they pertain to a broad program of grant and contract supported activities. In his role as NCI representative on the NIH Review Policy Committee (RPC), he is responsible for advising both the Division Director and the Institute Director on research contract, grant and training review policy. He is also actively involved in the coordination, planning and development of broadly based Division projects and serves as a principal technical advisor on the developmental aspects of Institute programs. He is currently chairing a working group assigned the responsibility of assessing the status of implementation and response of peer review to the recently issued Program Project Grant (P01) Guidelines.

Associate Director for Program Coordination (ADPC). The ADPC has primary responsibility in assisting the Director and Deputy Director, DEA, in integrating the functions of the Division with those of other NCI activities. For example, he functions as: the Institute RFA Officer; coordinator of the Institute's Small Business Innovative Research (SBIR) program; the division's representative to the NCI Chiefs of Project Officers (COPOs) and Chiefs of Program Directors (CPDs); coordinator for the Institute's annual November presentation of the divisional program reviews before the NCAB; the Institute's contact person for inquiries from the academic community regarding the NIH Academic Research Enhancement Award (AREA) grant program; coordinator for the revision of the Institute's description of extramural programs and associated budget levels for the Catalog of Federal Domestic Assistance; coordinator for the revision of the NCI program descriptions for inclusion in the annual NIH extramural program booklet; and Chairman for the ad hoc committee on secondary review of fellowship grant applications.

Office of the Director Activities

Outstanding Investigator Grant. The Outstanding Investigator Grant is in its second year as a new grant mechanism. It is intended to provide seven years of support to an investigator who has been conspicuously productive in research in the recent past. The second round of applications were assigned to programs by the Special Review Officer and were reviewed using the more flexible format of ad hoc mail review. Forty-seven OIG applications were reviewed, of which 21 will be awarded.

Requests for Applications (RFAs). During this fiscal year, 14 RFAs, including 5 by the cooperative agreement mechanism, and 13 Program Announcements were processed and cleared for publication in the NIH Guide to Grants and Contracts.

Small Business Innovative Research (SBIR) Program. Implementation of the SBIR program with other NIH BIDs through the solicitation of grant applications and contract proposals involves the drafting and verifying, with program staff of NCI and other Institutes, the subject criteria for approximately 75 program areas of the Institute which are consistent with the goals of the SBIR; responding to inquiries by prospective applicants of the small business research community concerning all aspects of the SBIR program; and tracking the progress of peer review of grant applications and contract proposals as well as the number of awards issued by the Institute. NCI is expected to meet the specified amount (11.3 million dollars) of its research and development budget for awards in the SBIR program for this fiscal year.

Personnel Actions

During the past fiscal year, several key personnel actions occurred within the Division involving the Office of the Director, the Grants Review Branch (GRB) and the Administrative Management Branch (AMB). These new appointments parallel an ongoing review of operational procedures and organizational structure so as to enhance the Division's capabilities for conducting and coordinating the grants and contracts review activities of the Institute in a responsive and timely manner.

- o Dr. Paul C. Rambaut became Deputy Director of DEA after establishing himself as an outstanding nutritional biochemist, physiologist and administrator, for both program and review activities, at the National Aeronautics and Space Administration over the past 18 years.
- o Dr. Robert F. Browning, newly appointed Chief of the Grants Review Branch, was formerly a Program Director for the Cancer Centers Program in the Division of Cancer Prevention and Control and gained prior grant review experience in DEA as Executive Secretary for the Cancer Control Review Committee. Dr. Browning's areas of scientific expertise are biology and invertebrate zoology.
- o Dr. Paulette S. Gray, Special Review Officer, was transferred to the Office of the Chief, Grants Review Branch where she will continue to function in the role of Executive Secretary for special grant initiatives, such as the Outstanding Investigator Grant (OIG). Dr. Gray also serves as the Institute's Conference Grant Coordinator.
- o Mr. Lawrence J. Ray, who was appointed Chief of the Administrative Management Branch, comes highly qualified to assume his new role based on previous experience as an Administrative Officer with the Division of Cancer Treatment and the Office of Personnel Management as well as a Budget Analyst in the NCI Budget Office and a Legal Assistant in the Office of the General Counsel.

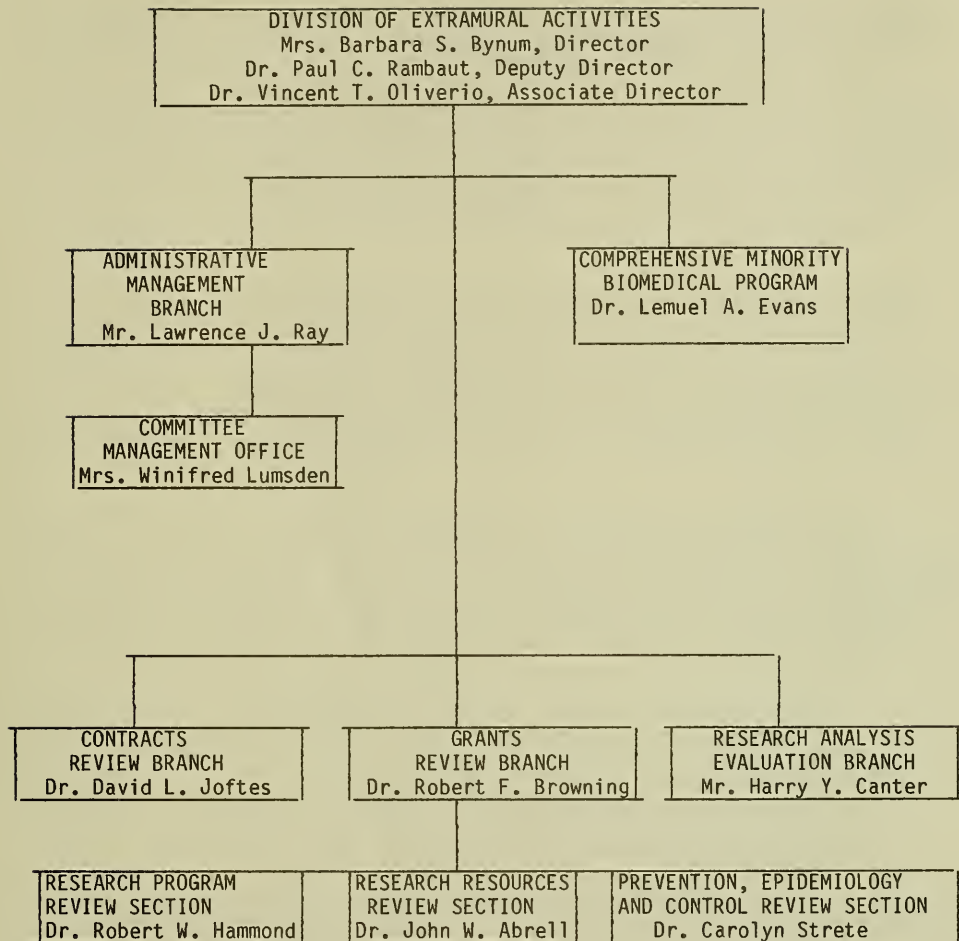


Figure 1.

ADMINISTRATIVE MANAGEMENT
BRANCH

Chief: Mr. Lawrence J. Ray
Deputy Administrative Officer: Mrs. Annette Romanesk
Committee Management Officer: Mrs. Winifred Lumsden

ADMINISTRATIVE MANAGEMENT BRANCH

The Administrative Management Branch (AMB) provides comprehensive administrative and management support activities for the Division of Extramural Activities; advises the Division Director and staff on administrative and management issues; plans and directs administrative and management functions of the Division in the areas of general administration, budget, personnel, contracts and interagency agreements, travel, office services, procurement, space management, training and other related administrative areas; advises and assists the Division staff on the legislative, procedural, and policy aspects of administration, and administers the committee management activities of the NCI. The Branch consists of the Administrative Office and the Committee Management Office (CMO).

On October 27, 1985 Mr. Lawrence J. Ray was appointed Administrative Officer for the Division of Extramural Activities and Chief of the Administrative Management Branch. The Administrative Office in Building 31 is staffed by an Administrative Officer who is also Chief of the Branch, Deputy Administrative Officer, Administrative Technician, Secretary, and a Stay-in-School. The Administrative Office in the Westwood Building consists of an Administrative Technician, a Grants Management Specialist, two Voucher Examiners, two Mail Clerks, and a Stay-in-School.

The AMB is responsible for the formulation, development, management and administration of the DEA budget, which is \$11,615,000 in Fiscal Year 1986. This includes \$2,882,000 for the Scientific Review and Evaluation Awards (SREA) to reimburse consultants for peer review of grants and cooperative agreements and contract proposals, \$3,611,000 for the Comprehensive Minority Biomedical Program, and \$5,122,000 to cover the direct operating costs of the Division.

The Administrative Officer is co-Project Officer on two contracts which support the DEA and other NCI components. Technical Resources, Inc. provides support services in the performance of numerous planning and analytical tasks including data collection and analysis as well as general logistics support for the National Cancer Advisory Board (NCAB) and the development of related or otherwise required documentation for conference activities of the DEA, Grants Administration Branch (GAB), and Extramural Financial Data Branch (EFDB). Automated Data Processing (ADP) activities are supported by a contract with General Software Corporation. These activities include systems design, programming, data entry, system documentation for users and programming, training of staff to use new and/or modified systems and ongoing technical support to users for day-to-day problems, enhancements and improvements which may be required. Approximately \$211,000 will be expended for these contracted activities in FY 1986.

The AMB is responsible for providing logistical support for the NCAB meetings and its members. This includes arrangements for travel orders, reimbursement for travel expenses, and payment of salaries for Board members conducting NCAB related activities.

The DEA Awards Committee, chaired by the Administrative Officer, received 17 quality step increases and two individual cash awards for consideration during FY 1986. The Committee's recommendations were approved by the Division Director, and subsequently 19 awards were presented during the year to DEA personnel. In addition, there was one PHS Award presented to a Commissioned Officer in DEA.

Technology Applications, Inc. in conjunction with the Office of Program Planning and Analysis, NCI are in the process of conducting management reviews of the Division to help improve overall operational efficiency. They have completed reviews of the Committee Management Office, the Board Preparation Unit, the Grants Referral Office, and are currently finalizing the review of the Research Analysis and Evaluation Branch. The Administrative Management Branch is being reviewed in conjunction with the OD, DEA with a final report scheduled this fiscal year or early in FY 1987.

As part of the management reviews, the Administrative Management Branch is coordinating an overall effort to automate Division functions and improve productivity. It is anticipated that the introduction of personal computers into the overall DEA work setting will further enhance the programmatic, review, and administrative management functions of DEA. Plans include automated links to commercial and government data bases; Intra-NCI/NIH data systems and internal linkages between DEA operations for the electronic retrieval, storage, transfer and development of administrative management systems to support the review mission of the NCI.

The activities of the CMO encompass the development and implementation of policies, guidelines, and procedures for the establishment, nomination, and appointment of members to approximately 23 chartered NCI review and public advisory committees requiring the services of some 425 committee members. This office is also responsible for Committee Management support to the Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Agent Orange), a committee of the Office of the Secretary, HHS. Committees are divided into two broad categories--scientific review groups and advisory groups. The primary function of the scientific review groups is to determine the scientific merit of research grant applications and contract proposals. The program advisory groups provide broad perspective on the research needs and scientific opportunities of the Institute and their social and biomedical impact.

The CMO is staffed by a Committee Management Officer, Committee Management Assistant, and a Stay-in-School. It provides guidance to the Executive Secretaries of NCI committees and other NCI management staff to identify and resolve any potential problems in both the nomination and committee chartering process. The CMO prepares the Annual Report to Congress on committee activities and the status of each committee. It supports the NCAB meetings; provides background information at the meetings to each member; and provides data concerning the National Cancer Program to NCAB members as requested by NCI officials to keep them abreast of the activities of the NCI.

The CMO coordinates the preparation of the Financial Operating Plan for each committee, the NCAB, the President's Cancer Panel (PCP), and the Agent Orange Advisory Committee. The total overall Federal staff costs and operating costs for maintaining these committees in 1986 was \$3,027,007. It also serves as the liaison for NCI to HHS and NIH regarding committee activities and coordinates the clearance of committee charters with the NIH Legal Office.

Charters for 14 of the committees including the NCAB and PCP will be renewed by September 15, 1986. An NCAB nomination package for the six vacancies was prepared this year and submitted to the Secretary, HHS for his approval and for subsequent approval by the President.

The CMO is now being evaluated by the Office of Program Planning and Analysis to automate CMO functions and improve communications between CMO and each of the committees. It is anticipated that overall office efficiency and productivity will be further enhanced by this effort.

COMPREHENSIVE MINORITY BIOMEDICAL PROGRAM

Director: Lemuel A. Evans, Ph.D.
Coordinator: Ms. Nola J. Whitfield

COMPREHENSIVE MINORITY BIOMEDICAL PROGRAM

Description

The Comprehensive Minority Biomedical Program (CMBP) effort of the National Cancer Institute has made significant progress in the area of minority involvement in cancer related research activities. The program reflects a broad-based approach to every aspect of the minority cancer problem with a particular focus on the cancer incidence mortality disparity between the black community and the general population. Increased funding for research by minority scientists; concerted enrollment of minority physicians and patients in clinical trials programs; cancer prevention and awareness heightening; and training and manpower development are part of this rapidly expanding endeavor. These activities have been implemented in line with the NCI overall effort at achieving national goals.

Background Information

The NCI CMBP was formed in 1975 through two Cooperative Agreements between NCI and (1) the Division of Research Resources (DRR) and (2) the National Institute of General Medical Sciences (NIGMS). Through the DRR agreement CMBP/NCI provides support for NCI mission-related projects of the Minority Biomedical Research Support Program (MBRS). The MBRS program provides expanded opportunities for ethnic minorities to choose and participate in biomedical research careers. The program awards institutional grants for the purpose of assisting faculty at minority institutions to develop biomedical research capability; enhancing the research potential of minority institutions in biomedical science; assisting in providing and developing an appropriate setting in which research activities can best be accomplished; attracting minority graduate students into biomedical research; and exposing minority undergraduates to biomedical research thereby motivating them to pursue research careers.

In a similar arrangement with NIGMS, CMBP/NCI support is provided to recipients of Minority Access to Research Careers (MARC) awards. The MARC program was set up to help minority institutions train greater numbers of scientists and teachers in biomedical disciplines. Four methods of funding are used to achieve this goal: faculty fellowships which provide opportunities for faculty members of 4-year minority colleges, universities, or health professional schools to pursue Ph.D. degrees or obtain postdoctoral training in the biomedical sciences; visiting scientists awards which provide financial support to outstanding scientists-teachers to serve as visiting scientists at minority institutions; honors undergraduate research training, an institutional training grant program aimed at increasing the number of minority students who can compete successfully for Ph.D. degrees in the biomedical sciences and developing strong science curricula and research opportunities at minority schools; and predoctoral fellowships awarded to distinguished graduates of the MARC Honors Undergraduate Research Training Program to help cover living expenses, tuition, and laboratory supplies for these students while they pursue research training leading to the Ph.D. in a biomedical science.

The broader goal of NCI's minority program is to provide support to minority scientists to assist in providing increased opportunities for enlarging their capabilities in cancer research and to influence more minority scientists to develop careers as cancer researchers. The program also seeks to promote manpower development targeted towards minority shortage areas of specialization, specialized research training of minorities at NCI-supported centers of excellence, the involvement of affected minority populations in the implementation of cancer prevention and intervention programs, and the participation of minority patients in clinical trials and other treatment programs, especially at minority institutions and hospitals.

Cancer Minority Program Advisory Committee

The Cancer Minority Program Advisory Committee (CMPAC) continues to play a major role in developing NCI minority policy in recommending cancer-related MBRS and MARC applications for initial funding and in evaluating the progress of NCI-supported minority scientists in order to assess their continuing needs. The committee, advisory to the Director, NCI, Director, DEA, and Director, CMBP, exercises its responsibility in setting CMBP goals; in developing plans for their implementation; in serving as counselors and catalysts to those minority investigators and trainees already funded by the Institute; and in interacting directly with administrators, faculty, and students of minority institutions, particularly the historical black institutions and the minority health professional schools. The committee has demonstrated its willingness and determination to alter the status quo and to propose innovative approaches to increasing and assuring the continued involvement of minorities in the activities of the National Cancer Program.

The advisory committee contains representation from each of the Institute's programmatic Divisions and from the Review and Management Branches.

MEMBERS

Dr. Colette Freeman, Chairperson
Chief, Tumor Biology Section
Division of Cancer Biology and Diagnosis

Dr. Matti Al-Aish
Acting Chief, Diagnostic Imaging Research Branch
Division of Cancer Treatment

Dr. Faye Austin
Chief, Cellular Immunology Section
Division of Cancer Biology and Diagnosis

Dr. Michael Friedman
Chief, Clinical Investigations Branch
Division of Cancer Treatment

Dr. Jack Gruber
Chief, Biological Carcinogenesis Branch
Division of Cancer Etiology

Dr. David Jofte
Chief, Contracts Review Branch
Division of Extramural Activities

Dr. Olga Joly
Director, Cancer Education Training
Division of Cancer Prevention and Control

Dr. Brian Kimes
Associate Director
Extramural Research Program
Division of Cancer Biology and Diagnosis

Dr. Barney Lepovetsky
Chief, Cancer Training Branch
Division of Cancer Prevention and Control

Mr. Henry Montes
Executive Secretary for Board of Scientific
Counselors and Special Assistant for
Hispanic Cancer Control Program
Division of Cancer Prevention and Control

Dr. Paul Okano
Program Director, Molecular Carcinogenesis
Chemical and Physical Carcinogenesis Branch
Division of Cancer Etiology

Dr. Vincent T. Oliverio
Associate Director for Program Coordination
Division of Extramural Activities

CMBP STAFF

Dr. Lemuel A. Evans
Director, Comprehensive Minority
Biomedical Program
Division of Extramural Activities

Ms. Nola J. Whitfield
Coordination, Comprehensive Minority
Biomedical Program
Division of Extramural Activities

GAB STAFF

Mr. Leo Buscher
Chief, Grants Administration Branch
National Cancer Institute

Ms. Angelia Douglas
Grants Management Specialist
Grants Administration Branch
National Cancer Institute

EX OFFICIO MEMBERS

Mrs. Barbara S. Bynum,
Director
Division of Extramural Activities

Dr. Robert Browning
Chief, Grants Review Branch
Division of Extramural Activities

Dr. Paulette S. Gray
Special Review Officer
Division of Extramural Activities

Progress Report

The Minority Travel Award initiative was expanded to include applications from the American Society of Clinical Oncology (ASCO) participants. The ASCO fellowship as well as the American Association of Cancer Research (AACR) fellowship would provide support for minority researchers to attend the annual meeting. The intent of this award is to increase the attendance of minority scientists at the national meeting; to increase the participation of minority scientists at the national meetings; and to increase the participation of minority investigators in cancer research.

CMBP, in conjunction with the Office of Cancer Communications, is providing support for the development of a model for utilizing four year and community colleges in the dissemination of cancer information. The effort has been initiated in three institutions: Grambling, Louisiana; Clark College, Atlanta, Georgia; and Lane College, Jackson, Tennessee. These institutions were selected because of their unique settings and their location in areas targeted for cancer prevention awareness campaign activities. The beginning phase of the initiative involves the issuance of task order contracts for the purpose of obtaining the nature of minority information dissemination models. This information will be used to produce the rationale and parameters for a more specifically developed project concept.

The CMBP effort has been promoted by program staff and CMPAC members through presentations at meetings and staff visits to organizations and institutions during the past year. These include: The NIH Extramural Associates Program; The National Institute of Science meeting; The Minority Biomedical Research Support Symposium; The First Annual Symposium on "New Horizons in Cancer Chemotherapy and Treatment: A Focus on Special Populations; Three planning meetings of the Network for Cancer Control Research in Black Populations; The Sixteen Institutions Health Science Consortium Annual Meeting; Fisk University; The University of Pennsylvania; The Black Congress on Health,

Law and Economics; The Annual Meeting of the American Association for Cancer Research; The Annual Technical Assistance Conference at North Carolina A and T University; and the Annual Meeting of the National Medical Association.

A significant increase in future CMBP funding is projected for the support of ongoing activities and new activities involving minorities.

Minority Investigator Supplement

The Minority Investigator Supplement award is designed to encourage participation in cancer-related research by members of underrepresented ethnic American minorities and will enable the NCI/CMBP to provide additional funds to NCI grantees who initiate an application to support minority researchers in their cancer research projects.

Eligibility. Any domestic institution with an active cancer research grant is eligible to submit a supplemental application on behalf of a principal investigator for the exclusive purpose of including minority researchers in the project.

Minority Investigator. A minority investigator may be described as a U.S. citizen from an underrepresented ethnic American nationality (e.g., Black, Hispanic, Native American, Asian, or Pacific Islander). Minority investigators are expected to provide a complete curriculum vitae which includes a list of any research publications. The investigators may be affiliated with the applicant institution(s) or some other institution. The program is not intended to pay stipends for student trainees or support candidates lacking research background. Investigators must be willing to devote a minimum of 30 percent of their time to the research project.

Research Project. The proposed project for the supplement must be closely related to the currently funded research grant. It may represent an increased effort in an already approved objective of the research project or propose to enhance the effectiveness of the overall research. The nature of the research should provide minority investigators an opportunity to contribute intellectually to the program and to broaden their own potential. The scope of the project will generally be comprehensive enough to require at least two years for completion and the supplemental application should include such a research plan and projected budget sheets. With appropriate justification a one-year supplemental may be acceptable. No new supplemental applications will be accepted in the final year of the current award.

Support. Funding will be made in accordance with the usual NIH policy for supplements. Each minority investigator budget shall not exceed \$25,000 in direct costs and may not include equipment. Funding for the supplement is always contingent on funding of the parent grant.

Nine Minority Investigators were supported through the Minority Investigator Supplement mechanism.

Minority Satellite Supplement

The National Cancer Institute seeks to promote the participation of minority patients in clinical trials and other treatment programs, especially at minority institutions and hospitals, through the establishment of the Minority Satellite Supplement (MSS) of the Comprehensive Minority Biomedical Program.

The CMBP and the Division of Cancer Treatment (DCT), NCI, are cooperating in this interdivisional initiative to identify domestic institutions capable of accessing large numbers of minority patients on a regular basis into clinical treatment protocols for improving survival and cure rates. They would function as cooperative satellites of cancer centers, with or without cooperative group affiliation and community clinical oncology programs. Supplements would be provided to existing cooperative group or cancer center grants for support of data management, and relevant expenses.

Eligibility. Domestic institutions capable of accessing large numbers of minority patients on a regular basis, entering eligible patients on protocols, delivering therapy and following up patients may apply. These patients, largely Black, Hispanic, Native American and Oriental, have breast, prostate, cervical, lung, colon, head and neck cancers as predominant pathologies. As many of the patients would benefit from new methods of cancer treatment, the satellite institution would become an affiliate of an NCI-supported clinical trials program.

Funding. Funding will be made in accordance with the usual NIH policy for supplements. Awards will be issued on an annual basis for the duration of the project period of the parent award. Continuing support for each subsequent year of the project period will depend upon approval of a satisfactory annual progress report and proposed budget. Funding for the supplemental awards under this program is for the sole purpose of facilitating participation by institutions as described above. Institutions and hospitals funded by an MSS are not eligible for continued support under this mechanism beyond the project period of the parent grant.

Eight MSS awards involving ten satellites were supported through eight NCI grantees including the Eastern Oncology Group; The Children's Cancer Study Group; The Northern California Oncology Group, The Florida Comprehensive Cancer Center and CALGB.

Travel Award for Young Investigators

A Comprehensive Minority Biomedical Program-American Association for Cancer Research (AACR)-sponsored travel fellowship provides support for minority student and faculty researchers to attend the annual meeting of the Association. The intent of the program is to increase the attendance of minority scientists at the national AACR/ASCO meetings and, in particular, to stimulate the participation of predoctoral and postdoctoral minority students in cancer

research. The award covers costs for registration, transportation, meals and lodging. Sixteen minority individuals from 15 institutions including two historically black colleges attended the May 1986 AACR/ASCO meetings in Los Angeles, California.

GRANTS REVIEW BRANCH

Chief: Robert F. Browning, Ph.D.
Special Review Officer: Paulette S. Gray, Ph.D.
Referral Officer: Hernon Fox, M.A.

RESEARCH PROGRAMS REVIEW SECTION

Chief: Robert D. Hammond, Ph.D.
Executive Secretaries: Pamela J. Baker, Ph.D.
Edwin M. Bartos, Ph.D.
Suzanne E. Fisher, Ph.D.
Melody Y. Lin, Ph.D.

RESEARCH RESOURCES REVIEW SECTION

Chief: John W. Abrell, Ph.D.
Executive Secretaries: David Irwin, Ph.D.
Mary Ann Sestili, Ph.D.
Cynthia L. Sewell, M.A.

PREVENTION, EPIDEMIOLOGY AND CONTROL REVIEW SECTION

Chief: Carolyn Strete, Ph.D.
Executive Secretaries: O.M. Meredith, Ph.D.
John H. Schneider, Ph.D.
(vacancy)

GRANTS REVIEW BRANCH

The Grants Review Branch (GRB) is responsible for: (1) internal NCI program assignment of all grant applications referred to the NCI from the Division of Research Grants, NIH; (2) assignment of grant applications for program projects, cancer center core support, construction, training, and other special-purpose grant applications to appropriate NCI review committees; (3) organization and management of the scientific merit review of the applications; and (4) preparation of summary reports of the evaluations and recommendations of each site visit and each committee review. The Branch also serves as liaison between the Division of Extramural Activities, NCI, and the Division of Research Grants, NIH, in matters related to grant review and referral.

Most investigator-initiated research grant applications (R01, R23, K04) and fellowship applications (F32, F33) are reviewed in the Division of Research Grants. However, a number of special grant mechanisms have been developed to meet the particular programmatic needs of the separate NIH institutes. In the NCI, the GRB provides for the initial peer review of a number of special grant instruments: P01 (program project grant); P30 (cancer center core support grant); C06 (construction grant); R03 (small grants); R18 (cancer control grant); R25 (cancer education grant); T32 (training grant); U01 (cooperative agreement); and U10 (cooperative clinical trials cooperative agreement). Other grant instruments are reviewed as special needs arise. With the expansion of special program initiatives and grant instruments reviewed within NCI, the portion of the total NCI extramural budget reviewed by the DRG now has dropped below 50 percent of the total; thus, the GRB now reviews over half of the NCI program dollars.

Applications are also received for ongoing NCI programs or in response to a Request for Applications (RFA) which cannot be reviewed by the chartered review committees due to workload or to the lack of appropriate scientific expertise. In this circumstance, ad hoc committees are formed to review these applications. Special Review Committees (SRC) are formed to review single applications which cannot be reviewed by a chartered committee due to conflict of interest considerations or the lack of appropriate expertise.

The appropriate balance and expertise of each committee, both chartered and ad hoc, are assured by the selection of members who are active investigators and are nationally and internationally recognized leaders in the disciplines relevant to the cancer problem. The breadth of expertise of each committee is determined by the specialty areas of the applications that it reviews. Committee recommendations are reviewed by the National Cancer Advisory Board as required by the National Cancer Act.

During the time period of this report, the DRG determined that it did not have sufficient resources to continue reviewing those RFAs that resulted in R01 grant applications. Thus the GRB must now review all applications submitted in response to RFAs. As a rule, applications received in response to each RFA are reviewed by a separate ad hoc committee, the composition of which is tailored specifically to the content of the applications under review. In the

past year, 225 applications received in response to 10 RFAs were reviewed in the GRB.

The costs of peer review activities in the GRB, beyond those of staff and staff support costs, are provided for by scientific review evaluation grants to the chairpersons of two of the review committees. These costs include travel, per diem and consultant fees provided to the many scientists who serve as expert consultants in site visit reviews, as members of chartered committees and as ad hoc reviewers on either special or chartered committees. These costs amounted to \$1,514,000 in the period covered by this report. To put this in perspective, it represents 0.12 percent of the amount requested of NCI and 0.25 percent of that recommended by peer review.

In the past year the GRB has undergone a reorganization that partitions its review activities among the three sections as described below. In addition, the position of Special Review Officer has been reassigned from the Office of the Director, DEA, to the Office of the Chief, GRB. The major function of the Special Review Officer is the overall planning, development, and coordination of the scientific and technical review of grants and cooperative agreements in support of new or special activities of NCI, such as the Outstanding Investigator Grant (R35); Conference Grant Program (R13's, T14's, T35's) and Minority Investigator Supplement (MIS). This re-alignment brings the review of all of the grant mechanisms of the NCI into the GRB.

RESEARCH RESOURCES REVIEW SECTION

This section encompasses four chartered review committees: 1) Cancer Center Support Review Committee (CCS); 2) Cancer Clinical Investigation Review Committee (CCI); 3) Cancer Research Manpower Review Committee (CT); and 4) Cancer Education Review Committee (CEC). The grant mechanisms reviewed by these standing committees are: P30 (cancer center core support applications, U10 (clinical trials cooperative agreements), T32 (training applications), and R25 (cancer education applications). In addition, with the current organizational structure of the Branch, this section will be responsible for the review of K08 (clinical investigator awards), C06 (construction applications) and U01 (community clinical oncology program applications).

The Cancer Center Support (Core) Review Committee (CCS) provides merit review of Cancer Center Support Grant applications submitted by comprehensive cancer centers, laboratory cancer centers and clinical cancer centers. The peer review activities of the CCS require that the Committee members have a broad knowledge of the basic sciences that contribute new information about the cause and prevention of cancer and of the clinical sciences involved in prevention, diagnosis, and treatment of cancer. In addition, a thorough understanding of the administration and organization of medical schools, universities and free-standing cancer research organizations is essential. Sensitivity to an institution's organizational and administrative strengths and deficiencies is important. Reviewers must be able to recognize those management practices that promote good research. Cancer Center Support Grant guidelines are available and are modified to reflect changes in the thrust of

the cancer centers program. The Committee consists of 20 members who have broad experience in basic and clinical oncologic research and matters of fiscal, administrative, and biostatistical support. They provide advice to the Director, NCI and the NCAB concerning the merit review of Cancer Center Support Grant applications.

The Cancer Clinical Investigation Review Committee (CCI) has as its major function the review of applications for support of cooperative clinical trials and related areas of cancer research. The review of cooperative clinical trials requires that the reviewers be sensitive not only to the usual issues of scientific merit of clinical research, but to the special problems involved in cooperative research where the standardization and effective management of clinical research efforts at multiple institutions, sometimes distributed over wide geographic distances, are also important factors. Review by this Committee provides the NCAB and the Director, NCI, with recommendations concerning the opportunities and problems regarding the clinical assessment of chemotherapeutic agents and multimodality approaches to therapy. The committee consists of 24 members selected primarily from the areas of medical oncology, pediatric oncology, surgical oncology, gynecologic oncology, radiation therapy, pathology, and biostatistics.

The Cancer Research Manpower Review Committee (CT) provides advice to the Director, NCI, and the NCAB concerning the technical merit of National Research Service Awards which are institutional, multidisciplinary cancer research training grant applications. The Committee has 20 members with expertise in the basic and clinical sciences relating to cancer etiology, prevention, detection, diagnosis, and treatment.

The Cancer Education Review Committee (CEC) was chartered in February 1984. This Committee was formerly the Professional Oncology Education Review Committee and the Clinical Cancer Education Review Committee. This Committee reviews applications for grants to stimulate and expand multidisciplinary efforts in cancer education at various educational levels so that physicians, dentists, nurses, epidemiologists, and cancer prevention professionals deal more effectively with the clinical aspects of cancer. The Committee consists of 15 members with special expertise in a variety of cancer education programs. It provides advice to the Director, NCI, and the NCAB regarding the quality of the proposed education programs.

RESEARCH PROGRAMS REVIEW SECTION

This section includes three chartered committees: 1) Cancer Preclinical Program Project Review Committee (CAK); 2) Clinical Cancer Program Project Review Committee (CCP); and 3) Cancer Therapeutics Program Project Review Committee. Special and ad hoc review committees are also utilized as necessary. The program project (P01) grant is the predominant mechanism reviewed by this section, but others may be reviewed by special arrangement so long as their focus is preclinical or clinical cancer research.

the cancer centers program. The Committee consists of 20 members who have broad experience in basic and clinical oncologic research and matters of fiscal, administrative, and biostatistical support. They provide advice to the Director, NCI and the NCAB concerning the merit review of Cancer Center Support Grant applications.

The Cancer Clinical Investigation Review Committee (CCI) has as its major function the review of applications for support of cooperative clinical trials and related areas of cancer research. The review of cooperative clinical trials requires that the reviewers be sensitive not only to the usual issues of scientific merit of clinical research, but to the special problems involved in cooperative research where the standardization and effective management of clinical research efforts at multiple institutions, sometimes distributed over wide geographic distances, are also important factors. Review by this Committee provides the NCAB and the Director, NCI, with recommendations concerning the opportunities and problems regarding the clinical assessment of chemotherapeutic agents and multimodality approaches to therapy. The committee consists of 24 members selected primarily from the areas of medical oncology, pediatric oncology, surgical oncology, gynecologic oncology, radiation therapy, pathology, and biostatistics.

The Cancer Research Manpower Review Committee (CT) provides advice to the Director, NCI, and the NCAB concerning the technical merit of National Research Service Awards which are institutional, multidisciplinary cancer research training grant applications. The Committee has 20 members with expertise in the basic and clinical sciences relating to cancer etiology, prevention, detection, diagnosis, and treatment.

The Cancer Education Review Committee (CEC) was chartered in February 1984. This Committee was formerly the Professional Oncology Education Review Committee and the Clinical Cancer Education Review Committee. This Committee reviews applications for grants to stimulate and expand multidisciplinary efforts in cancer education at various educational levels so that physicians, dentists, nurses, epidemiologists, and cancer prevention professionals deal more effectively with the clinical aspects of cancer. The Committee consists of 15 members with special expertise in a variety of cancer education programs. It provides advice to the Director, NCI, and the NCAB regarding the quality of the proposed education programs.

RESEARCH PROGRAMS REVIEW SECTION

This section includes three chartered committees: 1) Cancer Preclinical Program Project Review Committee (CAK); 2) Clinical Cancer Program Project Review Committee (CCP); and 3) Cancer Therapeutics Program Project Review Committee. Special and ad hoc review committees are also utilized as necessary. The program project (POL) grant is the predominant mechanism reviewed by this section, but others may be reviewed by special arrangement so long as their focus is preclinical or clinical cancer research.

The Cancer Preclinical Program Project Review Committee (CAK) reviews applications requesting support of cancer-related program projects in the preclinical sciences. The Committee includes members with expertise in the basic sciences related to the cause, treatment, and prevention of cancer. The review also requires a thorough understanding of medical school and university organization; of the administration of large research programs; and a sensitivity to the effects on the applicant institution of large-scale research programs supported by sources external to the institution. The group advises the NCAB and the Director, NCI, regarding the scientific merit of the basic science program project grant applications submitted to the NCI.

The Clinical Cancer Program Project Review Committee (CCP) provides merit review of applications requesting support of clinical program projects. The review of large clinical research grant applications requires special expertise in cancer clinical trials; an understanding of the special demands of research with human subjects, of hospital and medical school organization, and of the administration of program projects; and, most importantly, detailed expert knowledge of the diagnosis and treatment of all types of cancer. The program project grant applications reviewed by this Committee are primarily concerned with radiation biology and therapy, cancer clinical immunology, and surgical oncology. The Committee provides advice to the Director, NCI, and the NCAB concerning the merit of program project grant applications in these areas of clinical cancer research.

The Cancer Therapeutics Program Project Review Committee (CTR) provides merit review of applications concerned with clinical and laboratory studies of cancer, the development and testing of new therapeutic agents and regimens, and the use of markers as diagnostic and prognostic indicators. The Committee consists of 20 members with expertise in medical oncology, synthetic chemistry, clinical and experimental chemotherapy, biochemistry, pharmacology, pathology, and other disciplines of relevance to clinical and laboratory cancer therapeutic research. The review activities of this Committee also require an understanding of the special demands of research with human subjects; of the requirements for use of Investigational New Drugs (IND); of medical school, university, and research institute organization; and of the administration of program projects. The Committee provides advice to the Director, NCI, and the NCAB concerning the scientific merit of the proposed program projects.

PREVENTION, EPIDEMIOLOGY, AND CONTROL REVIEW SECTION

This section plans, manages, and provides scientific merit review of applications addressing cancer prevention, epidemiology, and control by utilizing chartered and ad hoc review committees. Currently, the Cancer Control Grant Review Committee is the only chartered committee in this section. However, the growing number of applications received in epidemiology may soon justify a chartered committee to review these applications. A sizeable number of applications assigned to this section are received in response to special programmatic initiatives issued as Requests for

Applications (RFAs) which often require ad hoc review committees. A variety of grant mechanisms are assigned for review by this section.

The Cancer Control Grant Review Committee (CCG) reviews applications for grants involving research into methods to reduce the incidence, morbidity, and mortality of cancer. The methods proposed involve one or more of the full range of possible interventions -- prevention, detection, diagnosis, pretreatment evaluation, treatment, rehabilitation, and continuing care. The Committee is composed of 20 members, experienced in implementing cancer control programs, who represent specific disciplines in the clinical, behavioral, educational, analytical, and organizational aspects of cancer control. The Committee advises the NCAB and the Director, NCI, on the scientific merit of cancer-control grant applications.

GRANTS REFERRAL OFFICE

This office is responsible for the assignment of all grant applications to the most appropriate of the 37 separate NCI programs. During the past year, over 5,300 research grant applications (R01, R23, R43, and R44) were so assigned. Applications for the following mechanisms were also assigned to Initial Review Groups within the Branch: 82 program projects (P01), 18 cancer center core support grants (P30), 2 specialized cancer center grants (P50), 125 cooperative clinical trial grants (U10), 33 cancer control grants (R18), 15 construction grants (C06), 62 training grants (T32), 68 clinical investigator awards (K08), 14 education projects (R25), 165 small research grants (R03), 2 exploratory grants (P20), 101 cooperative agreements (U01) and 49 conference grants (R13).

The Referral Officer also serves as the NCI contact person for the extramural scientific community concerning both new initiatives announced as RFAs or Program Announcements such as the First Award, and also concerning general issues related to the grant application and review process.

Summary

The chartered, ad hoc and special review committees of the Grants Review Branch organized and managed the review of 816 grant applications requesting a total of \$1,257,286,000. Six hundred twenty eight (77 percent) were recommended for approval with budgets totaling \$594,404,000 or 47 percent of the total requested in all of the applications reviewed. The recommended budgets amount to 64 percent of the total requested in the applications approved. The review activity of the Grants Review Branch is presented in detail in Tables I-IV.

TABLE I

GRANTS REVIEW ACTIVITY - OCTOBER 1, 1985 through SEPTEMBER 30, 1986

(Dollars in Thousands - Direct Costs Only)

Committees	Applications Reviewed			Applications Approved			Overall Approval Rate	
	No.	\$ Requested	PSV*	No.	\$ Recommended	\$ Deleted	\$ %**	No. \$
CHARTERED COMMITTEES	322	554,291	76	233	276,687	199,453	58%	72% 50%
AD HOC COMMITTEES	463	562,306	12	367	230,590	71,989	76%	79% 28%
SPECIAL REVIEW COMMITTEES	31	140,635	30	28	87,127	59,951	59%	90% 62%
TOTAL	816	1,257,286	118	628	594,404	331,393	64%	77% 47%

*PSV - Project Site Visits.

** \$ % - Percent of \$ Recommended of \$ Requested in approved applications.

TABLE II

GRANTS REVIEW ACTIVITY BY CHARTERED COMMITTEES - OCTOBER 1, 1985 through SEPTEMBER 30, 1986
(Dollars in Thousands - Direct Costs Only)

Chartered. Comm.	Applications Reviewed			Applications Approved			Overall Approval Rate	
	No.	\$ Requested	PSV*	No.	\$ Recommended	\$ Deleted	\$ %**	No. \$
CAK (P01)	18	71,250	18	18	47,802	23,448	67%	100% 67%
CCG (R18, R03)	79	23,303	0	48	11,740	8,727	57%	50% 61%
CCI (U10)	110	121,403	14	63	32,250	23,071	58%	57% 27%
CCP (P01)	17	106,054	17	17	54,388	51,666	51%	100% 51%
CCS (P30)	13	105,021	13	13	64,221	40,800	61%	100% 61%
CEC (R25)	14	8,636	0	11	3,167	3,008	51%	79% 37%
CT (T32)	57	59,105	0	49	33,585	18,989	64%	86% 57%
CTR (P01)	14	59,249	14	14	29,534	29,744	50%	100% 50%
TOTAL	322	554,291	76	233	276,687	199,453	58%	72% 50%

CAK - Cancer Preclinical Program Project Review Committee
 CCG - Cancer Control Grant Review Committee
 CCI - Cancer Clinical Investigation Review Committee
 CCP - Clinical Cancer Program Project Review Committee
 CCS - Cancer Center Support Grant Review Committee
 CEC - Cancer Education Review Committee
 CT - Cancer Research Manpower Review Committee
 CTR - Cancer Therapeutics Review Committee

*PSV - Project Site Visits.

** \$ % - Percent of \$ Recommended of \$ Requested in approved applications.

TABLE III

GRANTS REVIEW ACTIVITY BY AD HOC COMMITTEES - OCTOBER 1, 1985 through SEPTEMBER 30, 1986

(Dollars in Thousands - Direct Costs Only)

Ad Hoc Committees	Applications Reviewed			Applications Approved			Overall Approval Rate	
	No.	\$ Requested	PSV*	No.	\$ Recommended	\$ Deleted	\$ % **	No. \$
Construction Grant (C06)	13	16,072	12	9	7,903	2,612	75%	69% 49%
Clin. Inv. Awards (K08)	74	17,398	0	61	11,778	2,711	81%	82% 68%
Outstanding Invest. Grants (R35)	47	152,315	0	47	116,240	36,075	76%	100% 76%
Conference Grants (R13, T14)	50	1,777	0	48	1,580	107	83%	96% 89%
Small Grants in Epidemiol. (R03)	24	598	0	16	389	9	98%	66% 65%
Urinary Bladder Cancer Network RFA 85-02 (U01)	21	4,518	0	21	3,350	1,168	74%	100% 74%
Small Grants in Cancer Control RFA 85-05 (R03)	77	1,796	0	52	1,178	2	100%	67% 66%
Biological Markers - RFA 85-06 (U01)	30	14,027	0	20	8,135	1,459	85%	67% 58%

(continued)

TABLE III (continued)

Applications Reviewed				Applications Approved			Overall Approval Rate		
Ad Hoc Committees	No.	\$ Requested	PSV*	No.	\$ Recommended	\$ Deleted	\$ **	No.	\$
Models of Biochem. Mod. RFA 85-13 (U01)	11	16,292	0	9	8,067	3,472	70%	82%	50%
Nat' Coll. Chemoprevention Projects RFA 85-15 (U01)	14	32,924	0	9	15,474	6,085	72%	64%	47%
Diff. Agents in Hu. Malignancies RFA 85-19 (R01)	14	6,360	0	11	4,661	615	88%	79%	73%
Retrovirus Vaccines RFA 85-20 (R01)	25	11,880	0	20	7,660	2,854	73%	80%	64%
Exog. and Endog. Retroviruses RFA 85-21 (R01)	18	5,966	0	17	4,485	1,288	78%	58%	52%
Ca. Control Dev. in Health Agencies RFA 86-01 (R10)	26	22,879	0	15	11,885	3,369	78%	58%	52%
NCDDG-AIDS RFA 86-05 (U01)	19	57,504	0	12	27,805	10,163	73%	63%	48%
TOTAL	463	562,306	12	367	230,590	71,989	76%	79%	41%

*PSV - Project Site Visits.

** \$ % - Percent of \$ Recommended of \$ Requested in approved applications.

TABLE IV

GRANTS REVIEW BY SPECIAL REVIEW GROUPS - OCTOBER 1, 1985 through SEPTEMBER 30, 1986
(Dollars in Thousands - Direct Costs Only)

SRC	<u>Applications Reviewed</u>			<u>Applications Approved</u>			<u>Overall Approval Rate</u>	
	No.	\$ Requested	PSV*	No.	\$ Recommended	\$ Deleted	\$ % **	No. \$
P01	24	100,075	24	22	62,262	37,580	62%	92% 62%
P20	2	2,187	1	1	1,723	140	92%	50% 79%
P30	3	23,349	3	3	16,131	7,218	69%	100% 69%
P50	2	15,024	2	2	7,011	8,013	47%	100% 47%
TOTAL	31	140,635	30	28	87,127	52,951	62%	90% 62%

*PSV - Project Site Visits.

** \$ % - Percent of \$ Recommended of \$ Requested in approved applications.

CONTRACTS REVIEW
BRANCH

Chief: David L. Jofte, Ph.D.

Executive Secretaries: Courtney Michael Kerwin, Ph.D.
Nabeeh Mourad, Ph.D.
Kendall G. Powers, Ph.D.
Harvey P. Stein, Ph.D.
Wilna A. Woods, Ph.D.

CONTRACTS REVIEW BRANCH

Introduction

This Branch is responsible for the peer review for technical merit of all research and development, scientific resource, and scientific support contract proposals submitted to the National Cancer Institute in response to Requests for Proposals (RFPs). RFPs for competitive or non-competitive procurements may emanate from any Intramural or Extramural Program, the Office of the Director, NCI, or the respective Offices of the Division Directors. Review of Interagency Agreement Proposals with research content is also a responsibility of the Branch. The latter are reviewed by procedures similar to those used for peer review of non-competitive contract proposals.

To meet its responsibilities the Branch uses five chartered committees, an intramural committee, and ad hoc review groups, as necessary. Ad hoc groups are used to avoid conflict of interest situations and/or to ensure review by peers with appropriate expertise.

Staffing

Each chartered committee is staffed by a Health Scientist Administrator (HSA) supported by a Contract Technical Assistant or a Contract Clerk. The Office of the Branch Chief is staffed by an HSA, his secretary, a Program Analyst, a Contracts Technical Assistant and a Mail and File Clerk. The Contract Technical Assistant provides additional support to any Executive Secretary who requires it due to heavy work load. In addition to their Chartered Committee assignments, the executive secretaries are assigned to organize and support ad hoc review groups according to workload and as their own scientific backgrounds suggest.

Operations

From data supplied in Table II one can calculate that 81% of the RFPs reviewed, or projected to be reviewed this year will have been reviewed by ad hoc groups. This compares with previous years of 51%, 44%, and 60%. Part of the increase reflects the large number of Small Business Innovative Research topics which are required by regulation to be reviewed by ad hoc groups. The potential conflict of interest of a chartered committee member if she/he is significantly involved in a proposal responding to a RFP which would ordinarily be reviewed by that committee is another reason for using an ad hoc group. A third reason is that the great diversity of projects which the Institute supports under contract will always require that a substantial fraction of the reviews be done by ad hoc groups simply because it is not possible to cover all the diverse types of expertise, some of which are only occasionally required, in chartered committees. Scientifically rigorous, thorough, impartial and timely review is assured whether a chartered committee or an ad hoc review group is used; each type has compensating advantages and drawbacks. The Branch has been able to meet its responsibilities using either system and we believe that good quality review has been achieved.

During this year all chartered committees were either brought to full strength or the nomination process for needed members is in the final stages leading to appointment of the last few members.

Reporting

The Branch publishes a monthly calendar of the review meetings to be held. The calendar shows tentative dates for review meetings three months in advance for all dates that are known. In addition, an internal status report for each RFP is prepared each Friday. RFPs are added to this report in the Request for Contract/Project Plan stage. This report is amended each week as new information is received or changes in status occur. The Branch staff uses this report to monitor progress and assess workload. This report, in conjunction with the computerized, pre-award tracking system used by the Research Contracts Branch, enables realistic planning to ensure timeliness of review.

Another report published monthly displays the number of days required to complete each major time component in the review process for each RFP reviewed. The time periods recorded are: number of days from date of receipt of proposals in the Branch to date of review meeting; number of days from date of review meeting to completion of draft minutes; and number of days from completion of draft minutes to date of submission of final, official minutes. This tracking enables staff to identify systematic delays and to seek ways of eliminating them.

Our objective is to achieve an average of 75 days from our receipt of proposals to the date of submission of the final, official minutes. Obviously, the relatively rare RFP which elicits a very large response of 30 to 50 proposals can not be completely processed within 75 days. RFPs with two to eight responses (the mean, mode, and median fall between 3 and 4 responses per RFP) can frequently be completed in less than average time. This year because of illness, temporary loss of support personnel, but mainly because of the very large increase in review activity there were many months in which our average slipped to 100-110 days. However, quality of review was maintained.

Interactions With Other NCI Staff

Staff of the Branch are aware of the importance of cooperative interactions with program and contracting staff. This year we continued the trend of replacing the full staff joint meetings of past years by smaller group meetings and discussions between individual executive secretaries and program and/or contracting officials. Cooperation and mutually supportive assistance have become the norm. Consequently many problems are avoided and mistakes prevented. This, in turn, contributes to better working relationships and more effective and timely work accomplishment. Without the cooperation of program and contracts personnel timeliness would have slipped even more this year.

Review Activities

This year the Branch reviewed both Phase 1 and 2 Small Business Innovative Research contract proposals. NCI published seventy-six Phase 1 scientific topics requesting contract proposals and 265 proposals were received in response. Eighty Phase 2 proposals will have been reviewed by the end of this reporting period. The Branch utilized 10 ad hoc groups to accomplish the initial technical evaluation. The Branch also assisted NIAID by reviewing proposals for AIDS research. All of this work was accomplished while the year's regular workload of 95 RFPs (578 proposals) continued to be processed.

Tables I and II together summarize the activities of the Branch. Table I displays the number of competitive RFPs and the number of proposals received in response to them, as well as the number of non-competitive, renewal contract proposals reviewed. Known totals of requested direct costs for the entire period of performance of each proposal are also shown. Because of the great variability in numbers of responses per RFP and the differences in direct costs of various contract projects, computation of averages is not informative and therefore averages have not been computed or displayed on this table.

Table II presents the number and types of review meetings held and the number of appointed or ad hoc consultants used. The table displays actual data covering the period up to the end of June 1986 and projected totals for the whole fiscal year. The actual data are reliable, and sufficient advance information is available to lend strong credence to the estimates for the whole year. The column on the right of Table II indicates that CRB will have used six per cent fewer meetings but one and one half times as many reviewers to review one and one half times as many proposals in FY 1986 as in FY 1985.

STATUS OF THE REVIEW COMMITTEES

Biometry and Epidemiology Contracts Review Committee. This committee advises the Director, NCI, as well as the Directors of the Division of Cancer Etiology, the Division of Cancer Prevention and Control, and the Division of Extramural Activities, on the technical merit of contract proposals responsive to RFPs related to cancer cause, epidemiology, biometry and prevention. The committee members must not only be experts in the various aspects of etiology, epidemiology and biometry, but they must also understand the problems and opportunities inherent in epidemiological studies. The consequences and implications of the Committee's recommendations affect a substantial part of the epidemiological research effort in cancer in the United States as well as other countries. This Committee is chartered to have 14 members, and is nearly at full strength. The Committee has been meeting as required.

Developmental Therapeutics Contracts Review Committee. This committee advises the Director, NCI, and the Directors of the Division of Cancer Treatment and the Division of Extramural Activities, on the technical merit of proposals for the development of therapeutically useful anticancer agents. The Committee is chartered to have 30 experts in the various fields and disciplines involved in drug development and biological response modifiers. The Committee is at full strength and meeting regularly.

Clinical Trials Contracts Review Committee. This committee advises the Director, NCI, as well as the Directors of the Division of Cancer Treatment and the Division of Extramural Activities on the technical merit of the contract proposals involving clinical trials and related studies. The committee reviews contract proposals from the other Divisions if they are clinical in nature. The committee is chartered to have 25 experts in the various fields and disciplines involved in clinical trials. Seventeen members are currently appointed and a slate of nominations for the remaining eight is being processed. The Committee was not called upon to meet this year. Members of the Committee did serve on ad hoc groups whenever their expertise was appropriate. A substantial number of RFPs for AIDS, LAK and other clinical trials are anticipated in FY 87, which will be assigned to this Committee for review, barring conflict of interest situations.

Cancer Control Intervention Programs Contracts Review Committee. This committee advises the Director, NCI, and the Directors of the Division of Cancer Prevention and Control and the Division of Extramural Activities on the technical merit of contract proposals in the fields of cancer prevention, detection, diagnosis, pre-treatment evaluation, treatment, rehabilitation, continuing care and professional and lay person continuing education. Committee members must understand not only the underlying science and clinical medicine involved, but also the implications for cancer control of the activities of significance in the prevention of cancer and the reduction of its morbidity and mortality. Much of the contracts activity involves behavioral science, social science, and education. Current indications are that there will be substantial activity in this area in the future. Therefore, the charter has been retained and the membership has been brought to full strength. The Committee met once this year. Additional reviews which ordinarily would have been assigned to this Committee were done on an ad hoc basis because of the need for expertise which was not available among the Committee members, a common problem in committee charges as broad as this Committee has.

Cancer Resources and Repositories Contracts Review Committee. This Committee charter was allowed to lapse in November, 1985, and the Committee's review responsibilities have been assigned to other chartered committees or ad hoc groups as appropriate.

Intramural and Administrative Support Contracts Review Committee. During 1981 it was determined that it was in the best interest of NCI to separate review of intramural support contract proposals from the program in the same way as extramural contracts review had been separated previously. In the expectation that review of intramural and administrative contract proposals would be best understood and accomplished by uninvolved Federal employees familiar with the activities requiring support, a committee composed of two subcommittees was authorized by the Director, NCI. Subcommittee A contains 20 members recruited from the senior extramural scientific personnel of NCI Branches which use support contracts. Members do not attend meetings when proposals for contracts for their own Branches are to be reviewed. Subcommittee B is composed of 10 NCI and NIH personnel with administration or information analysis competence and serves to review contract proposals in support of the administrative activities of the respective Offices of the Director, NCI, and the Division Directors. Appropriate Federal scientists from outside as well as within NCI and NIH are recruited for either Subcommittee as full members or consultants. The Committee is at full strength and the Subcommittees are meeting frequently. This is one of the more heavily used committees of the Branch.

Cancer Biology-Immunology Contracts Review Committee. This is the first year of operation for this Committee. The Committee advises the Director, NCI, the Director, DEA and the Directors of all the operational divisions on the technical and scientific merit of contract proposals concerning cancer biology and immunology as well as resources in support of associated research activities. The Committee is composed of 20 experts in the fields or disciplines of hematology, cellular biology, tissue culture, microbiology, genetics, veterinary medicine, animal husbandry, pathology and cellular and humoral immunology.

Some members of the de-activated Resources and Repositories Committee have been reassigned to this Committee, along with two immunologist members of the Developmental Therapeutics Committee. The committee is nearly at full strength in membership and has been meeting regularly.

TABLE I
CONTRACTS REVIEW ACTIVITY
OCTOBER 1, 1985 THROUGH JUNE 30, 1986 ^a

Review Groups	No. of RFPs	COMPETITIVE		NON-COMPETITIVE		Total Proposals	Direct Costs Requested	Direct Costs	Total Proposals	Direct Costs Requested
		No. of Proposals	Direct Costs Requested	No. of Proposals	Direct Costs					
Ad Hoc	45	296	\$424,607,862	14	\$4,074,594	310	\$428,682,456			
SBIR c	98	345		-						
Phase I	61	265	12,644,004	-		265	12,644,004			
Phase II	37	80	Not Available	-		80	Not Available			
Biometry and Epidemiology	3	20	15,055,497	9	5,433,127	29	20,488,624			
Intramural	2	2	1,009,132	-		2	1,009,132			
Cancer Biology and Immunology	4	4	4,720,989	-		4	4,720,989			
Developmental Therapeutics	8	64	33,781,348	-		64	33,781,348			
Cancer Control Intervention Programs	3	8	0	-		8	0			
TOTAL	163	739	\$491,818,832	23	\$9,507,721	762	\$501,326,553			

a) As of June 30, 1986, there are 18 additional competitive RFP's remaining to be reviewed in fiscal year 1986.
A reliable projection as to the number of responses and their direct costs cannot be made at this time.
These RFP's are completely excluded from the table.

b) Direct costs requested for the entire proposed contract period.

c) Each topic treated as a separate RFP.

d) No costs were requested because these are Master Agreements

TABLE II**MEETINGS HELD AND NUMBER OF REVIEWERS USED IN FISCAL YEAR 1986**

	ACTUAL THOUGH JUNE 1986	PROJECTED FY 86	EST. TOTAL FY86/FY85
MEETINGS			
AD HOC (SBIRS)	30 22	36 24	
CHARTERED COMMITTEES	10	12	
SITE VISITS	1	1	
TOTAL	63	73	.94
REVIEWERS			
NOMINATED OR OFFICIALLY APPOINTED COMMITTEE MEMBERS	126	140	
AD HOC CONSULTANTS	398	488	
TOTAL	524	628	1.5
*RFPs REVIEWED BY:			
CHARTERED COMMITTEES	29	39	
NUMBER OF PROPOSALS	107	126 (estimate)	
TOTAL NUMBER OF RFPs	186	204	
AD HOC GROUPS	157	165	
NUMBER OF PROPOSALS	655	661 (estimate)	
TOTAL NUMBER OF PROPOSALS	762	787 (estimate)	1.5

* Each SBIR Topic is counted as a single RFP.

RESEARCH ANALYSIS AND EVALUATION BRANCH

Chief: Mr. Harry Y. Canter

Deputy Chief: Rosemary M. Cuddy

Scientific Analysis Section: Vivyan K. Barrett, Chief

Technical Section: Dianne G. Ostrow, Chief

RESEARCH ANALYSIS AND EVALUATION BRANCH

Overview of Branch Activities

The Research Analysis and Evaluation Branch (RAEB) serves as the official centralized source of scientific information on NCI-supported research projects. Members of the Branch analyze and index the scientific content of all grants awarded by NCI, as well as NCI contracts and intramural projects. They use GENIUS, an unparalleled computer system, for storage and retrieval of this information in order to answer requests on a daily basis. Branch members also monitor published results of research supported by grants through a unique literature surveillance program.

Information and reports prepared by the Branch are widely disseminated throughout NCI--to other Divisions, Office of the Director, Office of Cancer Communications (OCC), Financial Management Branch, and the International Cancer Research Data Bank; to other NIH organizations such as the Research Documentation Section in the Division of Research Grants (DRG), the RAEB in DRG, and the Office of Program Planning and Evaluation in the Office of the Director, NIH; to other NIH Institutes; and to other Government and private organizations. In addition, staff members compare pending grants and contracts to existing NCI-supported projects at the same institution to insure against project overlap and duplication of support.

Computer Information System: GENIUS

The heart of the operation of RAEB is GENIUS, which has been in use since 1975 and has served as a model for computer information systems in several of the other Institutes at NIH. In 1982, the Director of NCI recognized GENIUS as the official NCI information system for scientific and administrative data related to NCI programs. Last year, he designated the RAEB, in conjunction with the Financial Management Branch, as the official source of fiscal information on NCI extramural programs; such information, derived primarily from GENIUS, is available through the use of Special Interest Categories (SIC) and Anatomic Site/Percent values assigned by RAEB staff to each grant, contract and intramural project.

The bulk of the database consists of scientific data for NCI grants indexed according to fixed categories as well as specific keywords or phrases taken by the indexer from the text of the grant application. Fixed category indexing terms are continually being revised to reflect current scientific discoveries and trends. Recent additions include research animals and veterinary medicine, terms needed to reflect interest in animal welfare, resources and treatment.

All active grants, including new grants and renewals, are indexed as soon as possible after they are funded, sometimes within a month. All contracts active through February, 1986, have been indexed for the GENIUS system under the aegis of a contract let by RAEB. RAEB staff is now indexing the new contracts.

Other data available from the system include administrative data accessed from the IMPAC system of the DRG and an abstract of each grant from the CRISP system. The scientific and administrative data can be retrieved in a variety of formats in order to respond to inquiries and prepare reports.

When completely operational, GENIUS will include data from five separate computer information files: (1) active research grants and companion history file of terminated grants, (2) unfunded grants and history file, (3) active contracts and history file, (4) intramural research projects and history file and (5) training programs.

All scientific and administrative data on the active and history files are searchable on the computer. About 95 percent of the active grants, including new proposals and type 2 applications for continuing support, and 95 percent of contracts have been indexed.

The contracts file begins with contracts as of August 1, 1980. The contract database is currently dependent on the IMPAC system for administrative items. Any data not available on IMPAC can be supplied by the Contracts Management System, maintained by the Extramural Financial Data Branch (EFDB), Office of the Director, NCI. The EFDB is currently developing a system to update the IMPAC files on NCI contracts more often and on a regular basis. Once this system is in place, RAEB will be able to rely totally on IMPAC for administrative data on contracts.

After the GENIUS contracts file is completed, the training file will be automated. The intramural projects file, temporarily inactivated due to a lack of staff, was reactivated last year; it contains information on projects since 1977.

GENIUS is now maintained and operated solely by the Branch. However, the Division of Computer Research and Technology (DCRT) was instrumental in developing and implementing GENIUS and assists the RAEB in refining the system and making changes to reduce costs. This year, for example, a DCRT staff member wrote a mainframe computer program to produce tables for reports based on the SIC (Special Interest Categories) and Anatomic Site codes, assigned to each grant and contract by RAEB staff. The tables show the number of grants or contracts for a particular code and the amount of money awarded for that particular area of research or anatomic site.

Requests for Information

Requests for information to the RAEB are made daily and vary in complexity. Most are answered by using GENIUS as well as the files that contain codes for Special Interest Categories (SIC) and Anatomic Site. These special codes are increasingly used by staff; they greatly facilitate answering questions requiring information on the percent relevance of a project to a specific category or site.

Other sources of information are maintained and used by the Branch. These include copies of grant applications and contract proposals for active projects; progress reports; study section summary statements; and documents concerning training.

The Branch also has developed several unique files of information, including the Professionals File, which is almost totally computerized. It includes the names of principal investigators and numbers of their grant applications submitted to NCI, whether approved or not, and the names and grant support of all

other professional personnel (on awarded grants only). Contract information is included in some cases. This file is often used to answer requests from staff of the Review and Referral Branch who wish to find or verify the names of scientists with a particular expertise to send on site visits, and from staff of the Office of Cancer Communications (OCC) requesting total NCI support for an individual.

The number of requests for information reached 470 in calendar year 1985. More than one third (35 percent) came from OCC, Office of the Director, NCI, and included information to answer letters from the public as well as inquiries from members of Congress and the White House staff. This high percentage reflects increasing public awareness of NCI programs and the important role the RAEB plays in helping the OCC respond to a wide variety of requests.

The next largest number of requests came from the offices of the program directors in the various divisions of NCI--132 requests or 28 percent of the total, representing 10 percent more requests than last year. In many cases, the requests are for listings of NCI awards in important areas of research that may not be adequately funded. By obtaining such information, the program directors can evaluate the need to issue an RFA for grants or an RFP for contracts to satisfy poorly supported areas.

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Because of the continued high rate and complexity of requests, much more time and effort had to be spent this year in the information retrieval process, resulting in fewer staff hours available for scientific indexing of information for input into GENIUS.

During the past few years, the Branch has received numerous requests concerning long-expired NCI-supported research projects. The only source of information on NCI projects paid before 1960, when the Division of Research Grants computerized the data, is the NIH annual printed listings of extramural projects. Using these listings, as well as handwritten listings of unfunded applications compiled by the Branch more than 20 years ago, the RAEB has already entered almost half of the NCI historical data into a computer file. When completed and verified, the file will provide automated access to funded and unfunded research grants according to subjects in title, principal investigator, and institution back to the founding of the Institute in 1937. A member of DCRT staff will then write programs to produce this information on microfiche.

To keep track of current and past requests, avoid repetition, and analyze ways in which GENIUS is used and by whom, the requests are entered into the mainframe computer and put on microfiche. Data include the date, requester and statement of the query. Requests cover a wide range of topics from a variety of sources. Some examples are given in the table that follows:

INFORMATION REQUESTS TO THE RAEB, FISCAL YEAR 1986

<u>Request</u>	<u>Source</u>
1. Dietary intervention in stage 2 breast cancer	Office of Cancer Communications (OCC)
2. Grants on ovarian cancer antigen CA125	OCC
3. Grant support of Herpes simplex virus and oral cancer	OCC
4. Current projects on fish fatty acids	NCI Budget Office
5. Support for Epstein-Barr virus studies	NCI Budget Office for Senator Proxmire
6. NCI projects related to space medicine	Dr. Vincent DeVita, Director, NCI
7. Mortality reduction of cancer in black populations	Office of the Director (OD), NCI/ Congressional Liaison Office
8. NCI support for studies on smokeless tobacco	OD, NCI/Congressional Liaison Office
9. Types of animals used in biological carcinogenesis grants	Program Director, Division of Cancer Etiology, NCI
10. Diagnostic markers for prostate cancer	Program Director, Division of Cancer Prevention and Control, NCI
11. NCI programs in cancer prevention education aimed at junior high and high school students	NINCDs, NIH
12. Psycho-immunological aspects of AIDS and beta-carotene	Boston University

Personal Computers

Last year the Branch purchased and set into operation two IBM personal computers (pc) in order to help staff handle an ever-increasing workload. One of the first applications developed was for the Professionals File, which includes thousands of cards of information on professional personnel listed on all NCI grants, and in some cases contracts, going back as far as 1937. The data recorded on the file cards are now being entered directly into a WYLBUR file on the NIH mainframe computer by a contractor. New data are being entered into a personal computer by RAEB staff, who then transmit the data to the mainframe computer. All data are compiled, stored and retrieved from the mainframe using programs written by a member of DCRT staff. Once all the cards have been processed, RAEB will handle the entire job. This system will save much time, provide ease of data manipulation, free the space occupied by the file cabinets, and avoid problems of deterioration of paper files.

This year, Toby Friedberg, a member of RAEB staff, developed a system to index grants on the pc. With this system, an indexer can mark the fixed terms that best describe the scientific content of a grant and supplement these terms with specific keywords and descriptive phrases. The steps are similar to those done with paper and pencil, but the word processing features of computerized indexing allows greater facility for correcting errors, placing keywords in a logical sequence, and eliminating errors that result from misread handwriting. It also allows immediate incorporation of changes in the list of fixed terms since there is no wait for new cards of fixed terms to be printed.

Indexed information can also be more quickly incorporated into the GENIUS system because it can be transmitted from the pc to the mainframe computer as soon as the indexing is finished. This will eliminate the need for staff to prepare the handwritten information in a certain format and send it to keypunch at DCRT, steps now required to incorporate the data into the GENIUS system. It will also greatly decrease the time RAEB staff spends on proofreading the data entered by DCRT.

It is anticipated that the Branch will soon be able to order several more computers so that the entire professional staff will be able to index grants more efficiently.

In conjunction with the indexing of grants, Ms. Friedberg has developed a way to query a computer file that serves as a dictionary for definitions and indexing criteria. She is currently expanding the dictionary so it will contain definitions and information on all the fixed terms. She will later include other commonly used scientific concepts and terms.

Personal computers are also being used to download information each month from the National Library of Medicine's monthly updated file of literature in the area of cancer research. Journal articles retrieved are those supported by grants from NCI. This information is used to supplement the medical and scientific journals scanned each week by a member of the staff, as explained in the section on literature surveillance. The information from the NLM also includes MESH headings, which are terms that include the main ideas and areas of research covered by the article. Programs for the NIH mainframe computer

are now being written by a member of the DCRT so these headings can be used to augment titles used as the basis for the NCI-Grant-Supported Literature Index.

Information on projects with a special orientation can be easily and inexpensively stored and retrieved with personal computers. For example, at the request of the Division Director, RAEB developed a computer file in order to keep track of all investigators who have been awarded Minority Investigator Supplements, part of the NCI Comprehensive Minority Biomedical Program. As new awards are made, the names of the minority investigator and principal investigator, grant number, institution, title of project, and amount awarded to the minority investigator are entered into the file.

Special Projects

Branch staff continued to devote much time to requests to retrieve and analyze information for special programs and activities. Mr. Harry Canter, Chief of RAEB, and Ms. Rosemary Cuddy, Deputy Chief, along with other members of the staff, were directly involved in providing the necessary information.

Diet, Nutrition, and Cancer Program

Branch staff has continued to assist the Diet, Nutrition and Cancer Program (DNCP), established to coordinate all nutrition research supported by various NCI programs. The function of the nutrition program is to collect, analyze, and disseminate information on the interrelationships between diet, nutrition and the etiology of cancer and the therapy and rehabilitation of the cancer patient for the NIH-wide study on support of nutrition research.

Branch members played a significant role in helping the DNCP implement their information function. They identified all fiscal year 1985 grants, contracts, and intramural and training projects; estimated the percentage of dollars spent on each award for nutrition research relevant to the program; and provided these data in machine-readable form to the NIH Nutrition Coordinating Committee. This Committee is responsible for collecting all the NIH data on nutrition research as well as maintaining the Human Nutrition Research and Information Management System--an interagency computer data system. Branch members also supplied these data for the DNCP status report and for answering inquiries on NCI support of nutrition activities.

Digestive Disease Interagency Coordinating Committee

This year the RAEB again supplied data on NCI projects to the Digestive Disease Interagency Coordinating Committee. Staff members refined the computer programs in order to access a wider range of information and thereby produce reports more efficiently.

Special Interest Categories (SIC)

In recent years, the RAEB has been asked with increasing frequency not only to identify projects--grant, contract and intramural--in particular areas of research, but also to judge the degree to which each research area is covered

by each project. Consequently, RAEB staff has continued to analyze the GENIUS indexing and abstract of each NCI project for the percent relevance to special interest research categories, numbering 125 this year. The list of categories was originally compiled by the Financial Management Branch but is now being expanded by both the FMB and the RAEB.

RAEB staff continually analyzes NCI projects for the special interest categories as new projects are awarded and as the GENIUS indexing is updated for older projects. The category codes and assigned percent relevance become part of the record for each project. Funding for each category for grants and contracts is automatically calculated by the computer by multiplying the award for the total project by the percent relevance to the category in question; funding information for intramural projects may soon be available.

The special interest categories are updated continually to reflect subjects of growing interest to the public and to Congress. They are used throughout the year to answer inquiries in these areas. Among the categories currently considered to be of special interest are:

1. Tumor necrosis factor (TNF)
2. Ethylene dibromide
3. Behavioral research
4. Lymphocyte activated killer (LAK) cells
5. Information dissemination
6. Smokeless tobacco
7. Hyperthermia

Each grant project, in addition to being analyzed for relevance to SIC, is also analyzed for its degree of relevance to anatomic site(s) (Anatomic Site/percent values). Unlike the SIC, which are not always mutually exclusive, the total percent anatomic site relevance for each project must equal 100. Thus, the distribution of funds by anatomic site equals the total awards for all projects.

Human Genetic Resources

This year the Associate Director for Extramural Research Programs for the Division of Cancer Biology and Diagnosis requested that RAEB assist him in analyzing NCI grants and contracts for genetic resources. These are biological materials, methods, databases, and computer programs that are available to the scientific community for research in genetics. Examples include cell banks, DNA libraries, gene probes, clones, cancer family registries, and computer programs for sequencing nucleic acids and proteins.

This request is part of a Government-wide analysis of grants and contracts in an attempt to avoid duplication of support for already available genetic resources. Guidelines for use and strict definitions of these resources are now being formulated by representatives of various Government agencies. To keep track of these resources in the future, RAEB will add this category to the list of SIC codes and will add "genetic resources" to the list of fixed terms used to index NCI grants and contracts.

Literature Surveillance

Published results are monitored through the Branch's unique literature surveillance program. A member of the Branch scans each issue of 300 major medical and scientific journals and other periodicals to identify those reports resulting from NCI grant-supported or combined grant and contract-supported research. These references and additional references obtained from the National Library of Medicine's MEDLINE and from reprints submitted by grantees are entered into the computer system, which generates an alphabetical keyword in context (KWIC) index of the terms in the titles plus additional augmented terms.

In the process of augmenting, staff enters related or hierarchical terms which do not appear in a given title but are pertinent to the topic and are necessary for efficient retrieval. Terms are assigned by generic and specific categories as well as by their conceptual relationship to cancer and other research areas. Library and Professionals File data are used to verify information and ensure accuracy and subject relevance. This comprehensive augmentation incorporates the terminology of all scientific disciplines encompassed by cancer research.

The references are arranged according to NCI cancer activities and published monthly with a subject, author, and KWIC index as the NCI-Grant-Supported Literature Index. The Literature Index is the most complete record available within NCI of accomplishments of the total NCI extramural research grants program. As a computer-searchable system, it is used for yearly and monthly listings of current literature and for responding to requests from NCI staff and other members of the scientific community. In calendar year 1985, about 10,577 articles, representing the work of 15,944 authors, appeared in the index.

With the combined efforts of RAEB staff and a DCRT programmer, scanning of the literature, verification of the accuracy of the grant numbers used to identify NCI-supported research, and augmentation of the titles will soon be automated. Toby Friedberg has developed a system for automatically downloading into the personal computer each month a comprehensive listing of NCI-supported literature references from MEDLINE, and easily transmitting it to the mainframe computer; included with each reference are MESH headings or indexing terms that describe the areas of research covered in the article.

The DCRT programmer has written programs to arrange these references into a format suitable for the NCI-Grant-Supported Literature Index. She is writing additional programs to verify the grant numbers and supply the name of the principal investigator (PI), the PI's institute, and cancer activity data. Thus, the amount of time spent for scanning and data entry and the amount of time spent on verification of data will be greatly decreased. Other programs will allow the use of MESH headings as a way to curtail the amount of title augmenting done by the RAEB professional staff.

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